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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 19 2003

The Honorable Dianne Feinstein
United States Senate
Washington, DC 20510-0505

Dear Senator Feinstein:

Thank you for your letter of January 7, 2003, requesting the Environmental Protection Agency's (EPA or Agency) assistance in accelerating clean up efforts to reduce perchlorate contamination in California and in Colorado River water. I have been asked to respond to you as the Agency's Science Advisor.

The Agency is required by the Safe Drinking Water Act (SDWA) to use the best available science to support decisions about perchlorate and other drinking water contaminants. The Agency is now revising its perchlorate health risk assessment to establish a health risk benchmark known as a reference dose (RfD), which must be completed prior to consideration of the development of any legally enforceable drinking water or clean-up standard. Note that the RfD is not a drinking water standard or a clean up standard. Rather, it is one step in developing a broader response to perchlorate, which may ultimately conclude in the promulgation of a federal drinking water regulation for perchlorate.

EPA worked with various federal government agencies, including the Department of Defense (DoD), the National Aeronautics and Space Administration (NASA), and the Department of Energy (DOE) to develop a charge for the National Academy of Sciences' (NAS) review of the science underlying EPA's 2002 draft risk assessment for perchlorate. That 2002 draft risk assessment is based, in part, on scientific data generated through a targeted testing strategy to address key data gaps. That strategy began in 1997 and was developed by various federal government agencies and representatives from the defense industry. The current assessment has undergone two external scientific peer reviews, one in 1999 and the most recent in 2002. EPA is currently addressing recommendations from the 2002 peer review, as well as public and other government agency comments. However, the interagency group has agreed that an updated risk assessment will not be published until after the NAS review has been completed. Once the results of the NAS review are received, EPA will finalize the risk assessment, including the RfD for perchlorate.

When finalized, the RfD derived from that assessment would not be a legal standard for drinking water or site remediation, but would be only one critical piece of information used by EPA to establish a legal standard. Concurrently with evaluating the potential health risks, the EPA is also addressing other critical areas required to prepare for developing a water regulation. For instance, the EPA is analyzing national occurrence data to determine the location and magnitude of perchlorate in the environment. The Agency is also developing analytical methods to sample for its presence with reliability at lower concentrations and is evaluating treatment technology options for its removal from various water sources. This information will be used together with the RfD, once finalized, to determine what risk management steps to take, which may include the development of a national drinking water regulation for perchlorate. The same rigor that has been applied to the RfD process will continue to be applied to EPA's evaluation of the data on potential exposures, cost, efficacy of treatment technology, and reliability of analytical methods in order to evaluate risk management options for addressing perchlorate contamination.

As you may be aware, the Office of Solid Waste and Emergency Response (OSWER) recently sent a memorandum to its Regions regarding cleanup of perchlorate at Superfund and RCRA corrective action sites based on requests for clarification considering the most recent assessment activities (see enclosure). As has been Agency practice, while the results of the 2002 Draft Assessment are under review, the Agency has reaffirmed the 1999 Interim Guidance for Perchlorate. That guidance recommended that Agency risk assessors and risk managers continue to use the standing provisional RfD range of 0.0001 to 0.0005 mg/kg-day for perchlorate-related assessment activities. The 1999 Interim Guidance does not establish cleanup standards nor mandatory cleanup action levels. In the absence of site-specific risk assessment factors, this provisional reference dose range can be converted to a preliminary remediation goal of 4-18 ppb and is a screening tool and/or a point of departure for site-specific risk assessment decisions.

In selecting the actual cleanup level at a particular site, the Regions will continue to consider the factors that are typically addressed in setting groundwater cleanup levels, such as cost effectiveness, practicability, reliability of the exposure data, whether the groundwater is used as a source of drinking water, other routes of exposure, and current and future land uses. The Regions will continue to work with the States, as they have in the past. We recommend that the Regions continue to honor state standards through the CERCLA ARAR process, and in the case of RCRA, comply with more stringent state standards.

EPA Region 9 has been working closely with the Nevada Department of Environmental Protection (NDEP) and Kerr McGee Chemical Corporation (KMCC) since 1997 to reduce perchlorate releases to Las Vegas Wash (LVW) and Lake Mead. KMCC is extracting groundwater at three locations and treating it to remove more than 2,500 pounds of perchlorate per day. It is anticipated that, within one to three years, KMCC's releases of perchlorate to Las Vegas Wash and Lake Mead will be reduced significantly. On January 14, 2003, Kerr McGee

committed to install and operate three to six additional ground water extraction wells near Las Vegas Wash by early March 2003. These wells should provide additional reductions in perchlorate releases to Las Vegas Wash. EPA Region 9 will continue to discuss with NDEP and KMCC the feasibility of additional perchlorate removal opportunities in the Las Vegas Wash gravels if significant additional sources are identified.

The Office of Management and Budget has advised that there is no objection to the submission of this letter from the standpoint of the President's program.

Again, thank you for your letter. Should you have any questions, please contact me, or your staff may call Diane Hicks in our Office of Congressional and Intergovernmental Relations at (202) 564-3652.

Sincerely yours,

Paul Gilman

Paul Gilman, Ph.D.
Science Advisor to the Agency

Enclosure

January 22, 2003

MEMORANDUM

SUBJECT: Status of EPA's Interim-Assessment Guidance for Perchlorate

FROM: Marianne Lamont Horinko /SIGNED/
Assistant Administrator

TO: Assistant Administrators
Regional Administrators

The purpose of this memorandum is to provide information concerning the status of the interim assessment guidance for perchlorate originally transmitted on June 18, 1999 (the "1999 Interim Guidance"), a copy of which is attached to this memorandum for your information. This memorandum was developed in response to requests from EPA Programs, Regions and individual states for a clarification concerning the Agency's guidance in light of more recent assessment activities. Today, as an interim measure and in the absence of a finalized oral health risk benchmark for perchlorate, we are reaffirming the 1999 interim guidance. The 1999 interim guidance may be replaced upon finalization of the 2002 Draft Assessment referred to below.

Background

The US EPA has been working with states, federal agencies, tribes, water suppliers and the private sector for several years to address perchlorate as an environmental contaminant. Ammonium perchlorate, a component of, among other things, solid rocket fuel, fireworks, air bags and some fertilizers, is a widespread environmental contaminant. In 1998, EPA released an assessment of ammonium perchlorate which was then subject to peer review in 1999. The external review draft of the revised document, entitled, "Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization" (the "2002 Draft Assessment") responds to those recommendations emanating from the peer review.

The development of the 2002 Draft Assessment and the risk characterization activities have been subject to review by the working partnership of the Interagency Percholorate Steering Committee ("IPSC"), which is co-chaired by the US EPA and the Department of Defense, and comprised of representatives from more than 23 state, federal and tribal agencies. On January 18, 2002, the 2002 Draft Assessment was made available for a 77- day public comment period. An external scientific peer review workshop, open to the public, was held in Sacramento, CA, on March 5 and 6, 2002 to review the 2002 Draft Assessment and provide comments. These

comments are in the process of being addressed, and, over the next few months, the revised 2002 Draft Assessment document, including a recommendation for an RfD, will undergo further, focused review to address remaining issues and uncertainties Once these issues have been addressed, the document will be finalized and prepared for entry onto the Agency's repository of consensus risk information, the Integrated Risk Information System ("IRIS") At that time, we will consider the need for further guidance on this issue.

1999 Interim Guidance

On June 18, 1999, because of significant concerns and uncertainties that needed to be addressed in order to finalize a human health oral risk benchmark for perchlorate, the Office of Research and Development ("ORD") released the 1999 Interim Guidance That guidance recommended that Agency risk assessors and risk managers continue to use the standing provisional reference dose ("RfD") range of 0.0001 to 0.0005 mg/kg-day for perchlorate-related assessment activities. This range was originally issued by ORD's National Center for Environmental Assessment ("NCEA") Superfund Technical Support Center based on assessments completed in 1992 and revised in 1995. In the 1999 Interim Guidance, ORD stated, "If federal, state or local environmental authorities decided to pursue site-specific clean-up or other water management decisions based on this RfD range by applying the standard default body weight (70 kg) and water consumption level (2L/day), the resulting provisional clean-up levels or action levels would range from 4-18 parts per billion ("ppb") "

In the absence of a finalized oral health risk benchmark for perchlorate, but in light of ongoing assessment activities by EPA, states and other interested parties, we are re-affirming this guidance with an added suggestion to carefully consider the low end of the provisional 4-18 ppb range. The 1999 Interim Guidance remains the applicable guidance until supplanted by new guidance based on a finalized risk assessment. [1]

The uptake and elimination kinetics of perchlorate for children are such that traditional adjustment of exposure based on body weight scaling results in exposure estimates equivalent to those for adults. Concern for increased susceptibility of exposures throughout lifetime are addressed by the uncertainty factors used in arriving at the health risk benchmark. For these reasons, with respect to both a new oral health risk benchmark and the existing provisional clean up range of 4-18 ppb set out in the 1999 Interim Guidance no additional adjustment for childhood exposure is necessary.

Because of the complexity of the issues surrounding this assessment, Programs, Regions and states are encouraged to consult with ORD on the status of the emerging science and the progress toward finalizing an oral health benchmark value. Similarly, because of the complexity of the issues surrounding analytical methods and available treatment technologies as outlined

[1] The suggestion to carefully consider the low end of the 4-18 ppb range is based on the fact that recent analyses carried out by EPA and independently by the State of California suggest that a new oral health risk benchmark for perchlorate is likely to suggest provisional clean-up levels within or slightly below the 1999 Interim Guidance range Because pregnant women and the fetus in utero are the most sensitive populations of concern for perchlorate toxicity in these recent analyses, the standard default adult body weight and water consumption values would be applied in converting a new RfD to provisional clean-up levels in ppb

below, and because questions may arise as to the application of this guidance for site specific decision-making, Programs, Regions and States are encouraged to consult with Office of Solid Waste and Emergency Response ("OSWER") on these issues.

Regulatory Implications

The Office of Water ("OW") will use the RfD as a starting point for a rulemaking process under the Safe Drinking Water Act ("SDWA"). Before initiating that process, the statute requires that the Administrator make a determination that the regulation of perchlorate would represent a "meaningful opportunity for health risk reduction". As discussed below, EPA is gathering the necessary data to assess the exposure to perchlorate in public drinking water systems. No later than the spring of 2004, we anticipate data will be available to enable the Administrator to make such a determination. In the interim, prior to a determination whether to proceed with a rulemaking, the Office of Water may issue a Health Advisory (HA), an estimate of acceptable drinking water levels of a contaminant. It is not a legally enforceable standard but serves as guidance to Federal, State and local officials. A Health Advisory may be issued within six months of a final RfD.

By itself, an RfD does not determine the level of the an enforceable standard, but is the foundation for determining the public health target, the maximum contaminant level goal ("MCLG"). The MCLG represents a public health goal specifically set at a level of no known or anticipated adverse health effects with an adequate margin of safety. The SDWA then requires the Maximum Contaminant Level ("MCL")to be set as close to the MCLG as is technically feasible, taking cost and other factors into consideration. By requiring consideration of these additional feasibility factors, Congress specifically recognized that the MCL may not be as stringent as the MCLG. As part of Development of an MCL the Agency will also need to evaluate whether there are other sources of perchlorate exposure in addition to drinking water. The RfD represents a scientific estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to a human population including sensitive subgroups which is likely to be without appreciable risk of adverse health effects. It does not represent a "bright-line" between safety and risk. Because of the use of uncertainty factors in deriving the RfD so as not to underestimate the "safe" level, the specific level at which actual risk from exposure begins above the RfD cannot be precisely calculated.

While an RfD addresses the issue of protection from adverse health impacts, EPA must also gather occurrence data at public water systems, evaluate the availability and cost of treatment technology and, finally, assure that analytical methods are available for a range of different water matrices to measure perchlorate at whatever the ultimate MCL level may be. Simultaneous with development of a revised risk assessment, the Agency has been gathering and developing information to address each of these additional factors.

If the Agency decides to regulate perchlorate, the Agency has 24 months to propose an

MCLG and an MCL. Within 18 to 27 months after the proposal, EPA must publish a final rulemaking.

In the area of occurrence, perchlorate is being monitored under the Unregulated Contaminant Monitoring Rule ("UCMR") at all large water systems and a statistical sample of small systems. Data is also being gathered by the USGS, by States, and through several large research projects. The combined results of these efforts together with related data analysis is expected in the Spring of 2004.

With regard to analytical methods, OW is revising the methodology for EPA method 314.0 which will be more definitive for perchlorate and yield results in the sub-ppb range by isolating it from the matrix interferences, and avoiding possible resin contamination which might yield false positives In addition, OW and ORD are collaborating on a method coupling ion chromatography and mass spectrometry to achieve reliable results, again below 1 ppb. Results are expected in late 2003.

Finally with respect to evaluating available technology, a number of bench and pilot scale research efforts are underway to develop and refine treatment technologies for perchlorate. Ion exchange and biological treatment appear to be the most promising candidates at the moment. There are systems currently operative in California that use an ion exchange technology. Questions remain with respect to the performance of these technologies in different source waters with competing ions, microbial sensitivity, method for waste brine disposal or destruction for IX, and acceptability of using bacterial reduction of perchlorate for drinking water. For more information on available treatment strategies, you can consult http://cluin.org/perchlorate, a web page maintained by OSWER's Technology Innovation Office.

Cleanup Decisions at CERCLA and RCRA Sites

Although EPA's waste programs implement cleanups through several different authorities, they have the goal of operating within a "one-cleanup program" concept. Where different programs face the same environmental problem, we should strive for consistent technical approaches. Thus, as a general matter, we expect the regions, under CERCLA and RCRA, to take similar approaches in assessing risks from perchlorate in groundwater and in determining appropriate cleanup levels. Regardless of the authority under which perchlorate is addressed, the risks are the same. The guidance in this memorandum, therefore, is applicable to all OSWER programs.

Specifically, perchlorate has been found in groundwater at numerous facilities around the country where, for example, rocket propellants and explosives have been handled. Therefore, we encourage the regions to consider during the site assessment and characterization phase, the likelihood that perchlorate may be present at facilities that manufactured, tested, or disposed of solid rocket propellant, fireworks, flares, or other such materials commonly associated with perchlorate. We also recommend that CERCLA five-year reviews and standard RCRA oversight activities (e.g., permit modifications or renewals) at these types of facilities include steps to

determine whether previously undetected perchlorate is present at levels that may not be protective. In some cases, this may result in the need for additional followup in terms of monitoring and in some cases response actions to ensure protectiveness.

In determining whether cleanup may be necessary and in setting appropriate cleanup levels, the regions should follow the 1999 Interim Guidance described in the first section of this memorandum. As stated there, when based on the provisional RfD range, the regions should continue to use the provisional cleanup levels for perchlorate in groundwater ranging from 4 to 18 parts per billion ppb with an added suggestion to carefully consider the lower end of the provisional-range (as discussed earlier in this memorandum). Also, as noted earlier in this memorandum, the 4 to 18 ppb range is considered to be protective based on recent, ongoing analyses and taking into account the most sensitive receptors, and therefore no additional adjustment for childhood exposure is needed.

In selecting the appropriate cleanup level at specific sites, the regions should consider the factors that are typically addressed in setting groundwater cleanup levels, such as practicability, the reliability of exposure data, whether the groundwater is used as a source of drinking water, as well as other routes of exposure. Before a region, for site-specific reasons, chooses a cleanup level either below or above the 4 to 18 ppb range, it must consult with OSWER, ORD, and OW.

While this memorandum is intended for EPA regions, we encourage the regions to share its contents with the states. In addition, the regions should continue to honor state standards through the CERCLA ARAR process, and in case of RCRA comply with more stringent state standards.

Conclusion

To restate some of the points raised earlier in this memorandum, in the absence of a finalized oral health risk benchmark for perchlorate, but in light of ongoing assessment activities by EPA, states and other interested parties, we are re-affirming the 1999 interim guidance based on a provisional RfD range. Because an RfD represents a scientific estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to a human population including sensitive subgroups which is likely to be without appreciable risk of adverse health effects, it does not represent a "bright-line" between safety and risk, but provides a starting point for risk management decisions. Because women of childbearing age and the developing fetus are the most sensitive receptors for perchlorate exposures, the standard adult default body weight and water consumption factors apply in developing a range of provisional clean-up levels. Because of the approaches used to derive health risk benchmarks in recent analyses, no additional adjustment for childhood exposure is necessary.

cc: Tom Gibson
Claudia McMurray
Joe Martyak

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 18 1999

OFFICE OF
RESEARCH AND DEVELOPMENT

SUBJECT: Interim Assessment Guidance for Perchlorate

FROM: Norine E. Noonan Norine E. Noonan
Assistant Administrator (8101R)

TO: Regional Administrators
Regional Waste Management Division Directors
Regional Water Management Division Directors

The purpose of this memorandum is to transmit the attached interim assessment guidance from the Office of Research and Development (ORD) relevant to Agency activities related to perchlorate. The development of this guidance is in response to requests to ORD from some of the Regional offices, as well as from individual States.

As you know, the Office of Solid Waste and Emergency Response (OSWER) has recently forwarded to you the final report of the February 1999, External Peer Review of the document entitled "Perchlorate Environmental Contamination: Toxicology Review and Risk Characterization." The external review document (ERD), subject of the peer review, was developed by ORD's National Center for Environmental Assessment (NCEA).

The human health and ecological assessment issues related to environmental contamination by perchlorate are complex. The ERD addressed an immediate need to bring more science into the assessment process, but at the time of the February 1999 peer review meeting, several key studies on perchlorate were underway or planned. These studies will provide some critical assessment information. These new data will be incorporated into the revised assessment document that will undergo a second external peer review in January 2000. Because ORD is committed to bringing the latest available science to bear on the human and ecotoxicology estimates, ORD is recommending that until the completion of the second review, EPA risk assessors and risk managers follow the attached interim guidance. This guidance has been reviewed by the Office of Water (OW), Office of Solid Waste and Emergency Response (OSWER), and the Office of General Counsel and is supported by both OW and OSWER.

The Agency has committed to another external peer review as part of the process to more completely and accurately characterize the human and ecotoxicological risks associated with perchlorate contamination and to make this information available through the Integrated Risk Information System (IRIS). In the next assessment, NCEA will address comments made in the February 1999 report, as well as review and incorporate data from additional studies that were either nearing completion or recommended at that time. In addition to recommended studies on pharmacokinetics, developmental effects testing in another species and repeat motor activity evaluations are underway. Another important recommended activity underway is a National Toxicology Program-sponsored pathology working group (PWG) review of the thyroid and brain tissue from all previous and pending studies. This PWG review will provide for a common nomenclature of lesions and for a consistent pathology review across studies, with the goal to reduce variability in the data. Further, an interlaboratory validation study of the hormone analyses (T4, T3, and TSH) across participating laboratories will be performed. Additional ecotoxicology studies, including some site-specific and farm gate analyses of food crops, are also either being reviewed or already underway.

The purpose of the next external peer review will be to evaluate these additional data and to review the draft final NCEA assessment. All of the perchlorate testing and study activities, whether underway, in review, or planned, are being timed to support the goal of the next external peer review in January 2000 As mentioned above, this next peer review is intended as part of the IRIS process. After revision to reflect any additional comments or recommendations, the final NCEA assessment will then go to IRIS consensus review.

Because new analyses and data are to be considered, we can predict that the human and ecotoxicology benchmarks are likely to change. The new estimates will reflect greater accuracy and may be either higher or lower than the harmonized benchmark proposed in the February 1999 document (0.0009 mg/kg-day). *Therefore, ORD recommends that Agency risk assessors and risk managers continue to use the standing provisional RfD range of 0.0001 to 0.0005 mg/kg-day because of continued uncertainty with respect to the impact of the pending data and analyses on the final estimate* This recommendation helps to ensure that the Agency bases its risk management decisions on the best available peer reviewed science and is in keeping with the full and open participatory process embodied by the proposed series of peer review workshops. It should be noted, that due to the uncertainty of whether the final oral human health risk benchmark will increase or decrease based on the new data and analyses, the standing provisional RfD range is the more conservative of the estimates available at this time and, therefore, more likely to be public health protective in the face of this uncertainty. This is also consistent with Agency practice that existing toxicity estimates remain in effect until the review process to revise them is completed.

This document provides guidance to EPA Regions concerning Agency activities related to perchlorate. It also provides guidance to the public and the regulated community on how EPA intends to exercise its discretion in carrying out these activities. The guidance is designed to implement national policy on these issues. The document does not, however, substitute for EPA statutes or regulations; nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may change this guidance in the future.

We look forward to working with you as we come to closure on this aspect of the perchlorate contamination issues over the next nine months. If there are any questions or if you require additional information, do not hesitate to contact Annie Jarabek at 919-541-4847 (voice); 919-541-1818 (FAX); or jarabek.annie@epa.gov (E-mail).

Attachment

cc: Tim Fields, OSWER
Jonathan C. Fox, OW
William Farland, NCEA
Lt. Col. Dan Rogers, DoD
Annie Jarabek, NCEA

ORD Interim Guidance for Perchlorate

Because of remaining significant concerns and uncertainties that must be addressed in order to finalize a human health oral risk benchmark for perchlorate, the Office of Research and Development (ORD) recommends that Agency's risk assessors and risk managers continue to use the standing provisional RfD range of 0.0001 to 0.0005 mg/kg-day for perchlorate-related assessment activities. This recommendation is based on the determination that important new emerging data may have an impact on the proposed revised oral human health risk benchmark contained in the February 1999 External Review Document (ERD). Some background information and the reasons for this recommendation are detailed below.

In February 1999, an external peer review meeting was held in San Bernadino, California to review the document entitled "Perchlorate Environmental Contamination: Toxicology Review and Risk Characterization." This ERD was developed by ORD's National Center for Environmental Assessment (NCEA). The ERD, available on the Internet at http://www.epa.gov/ncea/perch.htm, was developed as part of a wider interagency effort to address environmental contamination issues related to perchlorate More information on this effort is available at http://www.epa.gov/ogwdw/ccl/perchlor/perchlo.html. The external peer review was sponsored by the Office of Solid Waste and Emergency Response (OSWER) and the Office of Water. The final peer review report of the February 1999 meeting has recently been transmitted to you by OSWER.

As explained in the ERD, the current range of a provisional RfD value for perchlorate spans from 0.0001 mg/kg-day to 0.0005 mg/kg-day; this range was issued by the NCEA Superfund Technical Support Center based on assessments in 1992 and revised in 1995. If state or local environmental authorities decide to pursue site-specific clean-up or other water management decisions based on this provisional RfD range by applying the standard default body weight (70 kg) and water consumption level (2 L/day), the resulting provisional clean-up levels or action levels would range from 4-18 parts per billion (ppb). It should be noted that no cancer assessment was performed at this time.

The ERD presented an updated human health risk assessment as well as a screening-level ecological assessment of newly performed studies on the toxicity of perchlorate. The updated health assessment harmonizes noncancer and cancer approaches to derive a single oral risk benchmark based on precursor effects for both neurodevelopmental effects and thyroid neoplasia. Both of these are historically established effects often observed after disturbances in the hypothalamic-pituitary-thyroid feedback system. By their nature, each of these effects is likely to have a biological threshold. The proposed revised oral human health risk benchmark is protective of potential carcinogenic effects based on new perchlorate data on the lack of its genotoxicity and the reversibility of induced thyroid hypertrophy/hyperplasia. The proposed revised oral human health risk benchmark is 0.0009 mg/kg-day. No traditional RfD or cancer slope factor was proposed in the ERD. If state or other local environmental authorities choose to apply the same default values as above to the revised oral benchmark, a site-specific clean-up or action level of 32 ppb would result.